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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/772,040	02/04/2004	Robert F. Rioux	03-253 US	3903

23410 7590 03/02/2007

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EXAMINER	
PEFFLEY, MICHAEL F	
ART UNIT	PAPER NUMBER
3739	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/02/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/772,040	RIOUX ET AL.	
	Examiner	Art Unit	
	Michael Peffley	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 January 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-46 and 57-67* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-46 and 57-61* is/are rejected.

7)☒ Claim(s) *62-67* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10 January 2005* is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Applicant's arguments, filed with the response of January 16, 2007, have been fully considered by the examiner. The following is a complete response to the January 16, 2007 communication.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 102

Claims 1-3, 6, 8-12, 15, 16, 18, 26, 27, 29, 31-35, 37-40, 57, 59 and 60 are rejected under 35 U.S.C. 102(b) as being anticipated by Chia et al (5,913,856).

Chia et al disclose an ablation probe that includes an elongate shaft (21 – Figure 2), an ablative element (11) disposed on the end of the shaft, a lumen extending within the shaft. The entirety of the shaft (21) is porous (col. 5, lines 25-45). Chia et al disclose pore sizes in the range of 5-1000 microns (col. 5, lines 28-29). The percent porosity is deemed to inherently be within the range as set forth in the claims, and the examiner maintains the Chia et al catheter may be broadly interpreted as being "rigid". Chia et al disclose an RF electrode as the ablation element, and also teach that the ablation electrodes may be made from a porous material. A pump is used to infuse fluid through the catheter (col. 5, lines 10-13). In view of the pore size disclosed by Chia et al, the structure is deemed to be "microporous" (see also col. 5, lines 29-30).

Claim Rejections - 35 USC § 103

Claims 7, 14, 19-21, 23-25, 30, 36, 41-46, 58 and 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chia et al ('856) in view of the teaching of Fung et al (6,602,242).

The Chia et al microporous catheter shaft has been addressed previously. Chia et al fail to specifically disclose pores that are interconnected. The examiner maintains that pores of such a size would inherently have an interconnected structure. However, to more accurately support such an assertion, attention is directed to the Fung et al reference.

Fung et al disclose another porous ablation catheter and specifically teach that pores in the perfusion electrode may be interconnected (see Abstract and col. 8, line 35) to provide better perfusion.

To have provided the Chia et al device with interconnected pores for providing the fluid through the porous member would have been an obvious design consideration for one of ordinary skill in the art, particularly since Fung et al teach that it is known to provide interconnected pores in a porous ablation device.

Claims 1-6, 8-13, 15-18, 26-29, 31-35, 37-40, 57, 59 and 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson et al (6,669692) in view of the teaching of Chia et al ('856).

The Nelson et al device includes an elongate shaft (60) having a distal end with an ablative element (52) disposed on the distal end. A lumen (65) extends through the elongate shaft and a porous structure (62) extends along substantially the entire length of the shaft. The only feature not expressly taught by Nelson et al is the size of the pores. Regarding the porosity, the examiner maintains that the percent porosity would inherently, or at least obviously, be located within applicant's claimed range to provide

the uniform fluid flow necessary to provide the uniform fluid flow necessary to cool the electrode. One of ordinary skill in the art would further recognize that the porosity could obviously be changed to provide the necessary fluid flow depending on the tissue being treated.

As addressed above, Chia et al disclose an analogous ablation probe having pores, and specifically disclose a range of pore sizes in the micron range that is acceptable for perfusing tissue during ablation.

With regard to claims 3 and 31, it is noted that the term "rigid" is a broad term. Nelson et al provide a plastic shaft that is rigid enough to provide support for the electrode, yet flexible to afford flexibility of the distal section. The plastic support shaft is deemed to meet the limitation "rigid".

Concerning claims 4 and 28, it is noted that the plastic catheter is surrounded by a wound electrode (61) which is metallic and has pores. The metallic electrode is deemed to be part of the porous elongate shaft.

Nelson et al provide a proximal connector for electrical and fluid connections, and inherently provides a means (i.e. a pump) to provide fluid through the catheter lumen.

To have provided the Nelson et al device with pores having a size in the micron range for perfusing the ablation electrode would have been an obvious design consideration for one of ordinary skill in the art since Chia et al teach that it is known to use such pore sizes in ablation perfusion catheters.

Claims 7, 14, 19-25, 30, 36, 41-46, 58 and 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson et al (6,669692) in view of the teachings of Chia et al ('856) and Fung et al ('242).

The combination of the Chia et al teaching with the Nelson et al catheter has been previously addressed. Also, the Fung et al teaching of providing interconnecting pores in a perfusion ablation catheter has been discussed.

To have provided the Nelson et al catheter, as modified by the teaching of Chia et al, with interconnected pores is deemed an obvious design consideration for one of ordinary skill in the art, particularly since Fung et al teach that it is known to provide perfusion devices with interconnected pores to provide fluid to tissue during an ablation procedure.

Allowable Subject Matter

Claims 62-67 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The prior art fails to disclose the particular probe having a porous shaft that is metallic in its entirety. The previously cited Brucker catheter had a metal, porous tip. However, there was no ablation element disposed on the

Response to Arguments

Applicant's arguments filed January 16, 2007 have been fully considered but they are not persuasive.

Initially, applicant asserts that the examiner has improperly examined the application *de novo* without consideration of the examination performed by the previous examiner. This assertion is without merit. The examiner now of record, is the same who indicated the allowable subject matter in the Final Office action of July 10, 2006. Only the Office action of December 14, 2005 was performed by another examiner, and that Office action included no indication of allowable subject matter. As such, the examiner has in no way failed to provide "full faith and credit" to the previous examiner's indication of allowable subject matter. Further, the examiner maintains that there was an error made in indicating allowable subject matter in the Final Office action of July 10, 2006.

As to applicant's assertion that the Chia reference is no more relevant that the previously cited Brucker reference (6,017,338), the examiner disagrees. Brucker fails to disclose a porous shaft with an ablative element on the distal end of the shaft as recited in the claims. Rather, Brucker et al disclose a metallic shaft that serves as an electrode. This is clearly distinct from the Chia reference whereby a porous shaft (21) includes a distal ablation electrode (11) disposed at the end of the shaft. Moreover, the examiner maintains that the Chia reference clearly discloses a shaft section disposed on the distal segment of the catheter, and that this "shaft" section may be deemed a separate element and is not merely the "distal end of the catheter" as asserted by the applicant.

On page 11 of the response, applicant suggests that the examiner has now rejected a variety of claims as being obvious over Nelson, alone or in combination with Chia. There are no claims in this or the previous Office action rejected under Nelson

alone, hence there has been no varying interpretation of the Nelson reference. Applicant has also asserted on this page that Chia teaches no more about the specifics of porosity than what was already disclosed in the previously cited prior art. Again, the examiner disagrees. Chia teaches very specific pore sizes for a perfusion catheter, and this specific teaching is deemed critical to making the rejections in the action. Moreover, as addressed above, Chia discloses the specific structure of a shaft made entirely of a porous material and having an ablation electrode at the distal end. As such, the examiner maintains that the Chia reference is clearly more relevant than the Brucker reference. And again, the examiner has not altered the position with regard to the Nelson reference. Rather, the examiner has modified the Nelson reference with the newly found Chia reference.

Concerning applicant's arguments directed towards the anticipation rejection involving Chia, applicant asserts that Chia only discloses that the tip section (6) is composed of porous plastic material. Column 5, lines 25-27 of the Chia patent states "Fig. 2 shows a close-up view of a distal section of the catheter with a porous shaft, wherein the pore sizes of the porous shaft range from 5-1000 microns." (emphasis added). From this disclosure, it is clear that the distal section of the catheter is it's own shaft, and the examiner has based the rejection on this interpretation. There is nothing in the claim language that specifically defines the shaft as not being attached to another structure, such as a catheter.

With regard to claims 3, 12, 31 and 37, the examiner maintains that applicant's definition for "rigid" is unduly limiting, particularly given the field of endeavor. Applicant's

needle certainly would not meet the strict definition of "devoid of flexibility" as elongate needles would certainly have some inherent capability of flexing. Moreover, the term "rigid" is a very subjective term, particularly in the medical art. Catheters are known to have varying degrees of flexibility depending on the usage. US Patent Numbers 5,242,441 (Avitall) and 5,8876,340 (Tu et al) disclose two catheters that are disclosed as being rigid. These device are clearly flexible to an extent, but relative to other catheters in the art they are deemed rigid for the designed purpose. The Chia ('856) catheter is particularly similar to the Tu et al catheter and is deemed to be rigid within the broadest sense of the term. Those of ordinary skill in the art would certainly recognize that the term "rigid" when used in a medical context would encompass a much broader interpretation than a strict dictionary definition.

As with the Chia reference, the examiner maintains that the Nelson reference does disclose a shaft that is porous along substantially the entire length. That this shaft may be connected to a catheter and the whole device is not porous does not preclude the Nelson device from reading on the claim language. Again, there is nothing in the claim language that would prevent the device from having an elongate shaft coupled to the end of a catheter if the catheter and the distal shaft section are deemed separate elements. The examiner maintains that Figure 2 clearly shows a distinct shaft member (54) coupled to a catheter, the shaft member being porous throughout its length.

Applicant has not argued the Fung reference except to state that it fails to cure the deficiencies of the Chia and Nelson references. The examiner maintains that the Chia and Nelson continue to read on the claims as asserted above.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is (571) 272-4770. The examiner can normally be reached on Mon-Fri from 6am-3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Peffley/

Michael Peffley
Primary Examiner
Art Unit 3739

mp
February 22, 2007